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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,090

04/29/2005

Norikazu Tabata

IPE-055

2293

20374 7590 02/06/2009
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EXAMINER

DICKINSON, PAUL W

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

02/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/533,090</p>	<p>Applicant(s) TABATA ET AL.</p>	
	<p>Examiner PAUL DICKINSON</p>	<p>Art Unit 1618</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 January 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 34 and 40.
Claim(s) withdrawn from consideration: 11-33,36,38,39 and 41-44.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/PAUL DICKINSON/
Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: The rejection of claims 34 and 40 under 35 U.S.C. 103(a) as being unpatentable over WO 2001072280 (WO '280) in view of US 7160551 ('551) in further view of US 6586354 ('354) is maintained.

Applicant argues that the properties of (A) "a water swelling ratio of 30% or more" and (B) "an elastic modulus in tension of 1500 MPa or less" are neither disclosed nor suggested by the combination of WO '280, '551, and '354. Applicant argues that the combination of water swelling ratio of the copolymer particles and tensile modulus of elasticity of the film are parameters resulting from adjustment of a complex combination of various elements, such as the ratio of hydrophobic segments and hydrophilic segments in the copolymer, the crystallinity of the hydrophobic segments, and the physicochemical interactions among the hydrophobic segments.

Applicant's arguments have been fully considered but are not found persuasive. WO '280 discloses the importance of optimum swellability of the copolymer. The copolymer of WO '280 has a swelling ratio of at least 100% (encompassed by the instantly claimed 30% or more). It would be obvious to optimize the swelling ratio to improve the efficacy of the embolization material. Applicant's means of achieving this is to adjust the relative amounts of hydrophilic and hydrophobic polymer segments, and also the degree of crosslinking, as seen in the Examples wherein different branched polyethylene glycols are used (see instant specification, Examples). Such adjustments are routine in the polymer art. Thus, the amounts of hydrophilic monomers present, the amount of hydrophobic monomers present, and the degree of crosslinking (taken from the Examples) are the only parameters used to adjust the swelling ratio. It would therefore be obvious to adjust these parameters to achieve a swelling ratio of 30% or more. The expectation of success is high, as WO '280 suggests such modifications (see page 20, lines 18-30; page 21, lines 13-27). As the parameters that control the swelling ratio (monomer amounts and degree of crosslinking) are the same as those that control the tensile modulus of elasticity, the swelling ratio optimized copolymer would inherently have an elastic modulus in tension of 1500 MPa or less. In other words, the claimed tensile modulus of elasticity is an inherent property of the film made from the swelling ratio optimized copolymer. This is supported by the table in Applicant's reply, wherein the only parameters adjusted are the amounts of hydrophilic and hydrophobic monomers added. A given amount of hydrophilic and hydrophobic monomer gives rise to a given swelling ratio and a given tensile modulus of elasticity. Furthermore, it is well known in the art that it is desirable to have a low level of stiffness in embolization materials. The tensile modulus of elasticity is a measure of the stiffness of an isotropic elastic material, usually defined as the ratio of the uniaxial stress over the uniaxial strain, higher values corresponding to increased stiffness. For the embolization material to migrate from one part of the body and cause blockage in another part, the material must have a low level of stiffness (corresponding to a low tensile modulus of elasticity).

Applicant argues that there are two other critical parameters: the crystallinity provided by the hydrophobic monomer and the physicochemical interactions among the hydrophobic segments. Regarding the crystallinity, Applicant argues that use of PLA with high crystallinity affords a high tensile modulus of elasticity and, if noncrystalline PLGA is present, the swelling ratio is high. The crystallinity Applicant is referring to is a property of the end polymer, and not the starting material, as the copolymer is prepared from lactic acid, not PLA, or it is prepared from lactic acid/glycolic acid, not PLGA (see Examples). WO '280 teaches PLA polyethylene glycol copolymers, and it would be obvious to use PLA in the copolymer. As the only parameters governing the final product are the amount of monomer and the degree of crosslinking (from the Examples), the water swelling optimized PLA polyethylene glycol copolymer would inherently have the required crystallinity. This is supported by the table in Applicant's reply, wherein a PLA-PEG-PLA is optimized to have a swelling ratio of 130 (30% or more) and a tensile modulus of elasticity of 230 (1500 MPa or less) (Example 1), and another PEG-8xPLA has a swelling ratio of 152 (30% or more) and a tensile modulus of elasticity of 100 (1500 MPa or less) (Example 6). Regarding the physicochemical interactions, a composition cannot be separated from its properties, and the physicochemical interactions among the hydrophobic segments would also be an inherent property in the swelling ratio optimized copolymer..